

510k Premarket Notification
POLYPERF® / POLYPERF® Safe

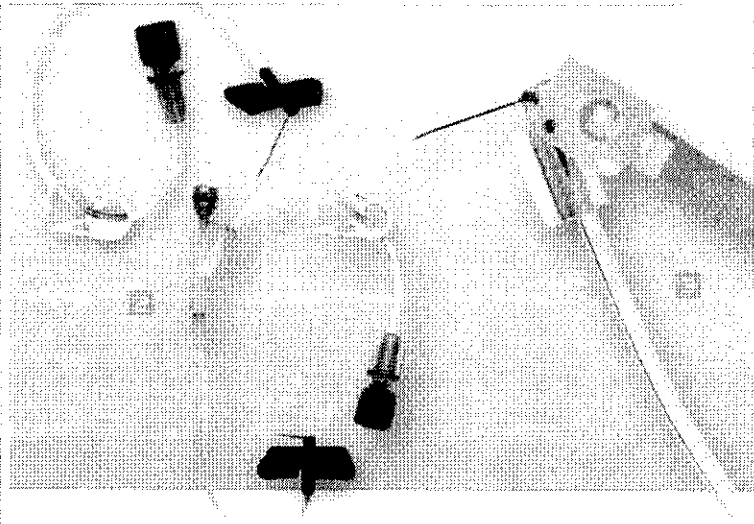


510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

OCT 5 * 2007

K063631

Submitter	Laboratoire PEROUSE Route du Manoir 60173 IVRY LE TEMPLE FRANCE Phone +33(0)3 44 08 17 00 Fax +33(0)3 44 08 17 01 Website: www.perouse.com		
Contacts	Marie-Noëlle EROUT – Quality Manager – e-mail marie-noelle.erout@perouse.com <u>Regulatory contact:</u> Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr		
Preparation date	August 22, 2006		
Trade Name	POLYPERF® / POLYPERF® Safe		
Common Name	Intravascular administration set		
Classification Name	set, administration, intravascular		
Legally marketed predicate devices	GRIPPER PLUS NEEDLE -DELTEC, INC - K021999 GRIPPER NEEDLE - DELTEC, INC - K896346		
Description	<table border="0"><tr><td><input checked="" type="checkbox"/> POLYPERF® Connection lines with Huber needle. Curved needle with luer lock and clamp with and without injection site.</td><td><input checked="" type="checkbox"/> POLYPERF® Safe Safety Huber needle with connecting line. Prevention of ABE. Easy to perform positive Pressure.</td></tr></table>  A photograph showing two medical devices. On the left is the POLYPERF set, which includes a curved needle with a luer lock and a clamp. On the right is the POLYPERF Safe set, which includes a safety Huber needle with a connecting line. Both sets are shown against a light background.	<input checked="" type="checkbox"/> POLYPERF® Connection lines with Huber needle. Curved needle with luer lock and clamp with and without injection site.	<input checked="" type="checkbox"/> POLYPERF® Safe Safety Huber needle with connecting line. Prevention of ABE. Easy to perform positive Pressure.
<input checked="" type="checkbox"/> POLYPERF® Connection lines with Huber needle. Curved needle with luer lock and clamp with and without injection site.	<input checked="" type="checkbox"/> POLYPERF® Safe Safety Huber needle with connecting line. Prevention of ABE. Easy to perform positive Pressure.		

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Intended Use	<p>POLYPERF® / POLYPERF® Safe connecting lines are indicated for the administration into or withdrawal of fluids from implanted ports.</p> <p>POLYPERF® Safe is designed to help protect against exposure to blood caused by accidental needle stick injuries.</p>
Performance data	<p>Performance data included with this submission</p> <ul style="list-style-type: none">✓ Biocompatibility✓ Safety and functionality testing✓ Clinical evaluation of the handiness and the safety of use of Polyperf® safe
Substantial equivalence	<p>POLYPERF® / POLYPERF® Safe connecting lines are substantially equivalent to their predicate devices in term of intended use and technological characteristics (materials, design and functionality).</p>
Conclusion	<p>Performance data demonstrates safety, effectiveness and substantial equivalence</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marie-Noëlle EROUT
Quality and Regulatory Affairs Manager
Laboratoires PEROUSE
Route du Manoir
60173 Ivry Le Temple
FRANCE

OCT 5 ' 2007

Re: K063631

Trade/Device Name: POLYPERF and POLYPERF[®] Safe
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FMI
Dated: September 10, 2007
Received: September 13, 2007

Dear Ms. EROUT:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,


Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510k Premarket Notification POLYPERF® / POLYPERF® Safe	 PEROUSE Laboratoires
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INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: POLYPERF® / POLYPERF® Safe

Indications for Use:

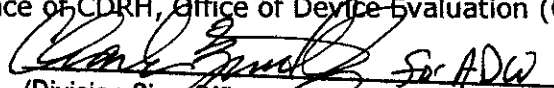
POLYPERF® / POLYPERF® Safe connecting lines are indicated for the administration into or withdrawal of fluids from implanted ports.

POLYPERF® Safe is designed to help protect against exposure to blood caused by "accidental needle stick injuries."

Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: KD6363/000012